

REMARKS

STATUS OF THE CLAIMS

Claims 112-162 were pending in this application. Claims 125 and 139-141 have been cancelled without prejudice. Claims 112, 123, 124, 128, 144, and 155-157 have been amended. Claims 163-165 have been added. Following entry of the amendments claims 112-124, 126-138, and 142-165 will be pending and at issue.

SUPPORT FOR AMENDMENTS TO THE CLAIMS

Claims 112, 123, 124, 128, 144, and 155-157 have been amended as shown above to more clearly define Applicant's invention. Support can be found throughout the specification as filed, e.g., at least at page 5, lines 11-13, 24-25, and 28-30 (paragraph 28 of the published application).

New claims 163-165 have been added. Support can be found throughout the specification, e.g., at least at claims 112, 128, and 144.

The amendments to the claims therefore add no new matter and entry is respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 112-162 were rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner stated:

Claim 112 recites the term analogue thereof. In the absence of the specific analogues recited via chemical structures or the chemical names, the identity of said analogs would be difficult to define and the metes and bounds of the said analogs applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in this and all other claims in which the said terms are recited. In the absence of a definition for the analogs in the claims or in the specification the said term is examined as drawn to any substance that has a L-carnitine moiety attached to it. The said terms are recited in claims 112, 128 and 144.

Office Action at 3.

Applicant disagrees. MPEP 2173.02 states that “[d]efiniteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.”

Applicant submits that analogs of L-carnitine were well known in the art at the time the instant application was filed. There are numerous examples of carnitine analogs disclosed in the scientific literature. Examples include: a cyclohexyl carnitine analog (Brouillette et al., *Acta Cryst.*, C51: 1160-1164, 1995; provided as Exhibit 1), a propionyl carnitine analog (Di Lisa et al., *Am. J. Physiol.*, 267: H455-H461, 1994; provided as Exhibit 2), carnitine tartrate (Volek et al., *Am. J. Physiol. Endocrinol. Metab.*, 282: E474-E482, 2002; provided as Exhibit 3), C₂-C₁₀ acylcarnitines (Cheng et al., *Biomedical and Environmental Mass Spectrometry*, 18: 668-672 (1989); provided as Exhibit 4), among others. These, and other references, indicate that a variety of analogs of L-carnitine were well known in the art at the time the instant application was filed.

Furthermore, the skilled artisan would also have had available dictionary definitions of “analog” to help guide the interpretation of this term at the time of filing. As an example, the Collins English Dictionary defined the chemical usage of the term “analog” as follows:

analogue *sometimes US, analog* ['ænə,lɒɡ]

4. (Chemistry) *Chem*

b. an organic compound that is similar in structure to another organic compound *thiols are sulphur analogues of alcohols*

See, Collins English Dictionary – Complete and Unabridged © HarperCollins Publishers 1991, 1994, 1998, 2000, 2003 (available online at: <http://www.thefreedictionary.com/analogue>).

In addition, the Examiner’s own arguments in the Office Action indicate that one of skill in the art could reasonably interpret the meaning of the term “L-carnitine or an analogue thereof” “at the time the invention was made.” See MPEP 2141.01. For example, the Examiner states at page 5 of the Office Action that “Pola teaches a composition comprising L-carnitine, propionyl

carnitine, acetyl carnitine, and isovaleryl carnitine (analogs of carnitine).” Office Action at 5.

Thus, “[t]he claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made” to the term “L-carnitine or an analogue thereof” would reasonably include an analog of L-carnitine defined as a structure that is similar to that of L-carnitine, e.g., the structures of “propionyl carnitine, acetyl carnitine, and isovaleryl carnitine.” *Id.*

In view of the above arguments this rejection is moot and withdrawal is respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 102

Claims 112-116, 118-122, and 161 were rejected under 35 U.S.C. § 102(b) as allegedly being unpatentable over Iaccheri et al (US 4,753,804; newly cited). Applicant traverses this ground of rejection by amendment and argument below.

Claims 112, 115, 117, 126-127, 144-154, 158-160, and 162 were rejected under 35 U.S.C. § 102(b) as allegedly being unpatentable over Brantman (US 4,687,782; newly cited). Applicant traverses this ground of rejection by amendment and argument below.

Claims 112-116, 118, 120-126, 128-132, 134, 136-142, and 155-157 were rejected under 35 U.S.C. § 102(b) as allegedly being unpatentable over Pola (WO 01/95915). Applicant traverses this ground of rejection by amendment and argument below.

Without agreeing with the Examiner, but merely to further prosecution, Applicant has amended the claims as shown above.

In order for a reference to anticipate an invention, the reference must teach each and every element of the claimed invention. None of the cited art teaches a composition comprising amounts of carnitine and an agent to increase blood/plasma insulin concentration that falls within the ranges described in the amended claims.

Accordingly, the cited art does not teach each and every element of the claimed invention as amended and cannot anticipate the claimed invention. Withdrawal of this rejection is respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 103

Claims 123-125, 128-143 and 155-157 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Pola (WO 01/95915; of record) in view of Brantman (US 4,687,782; newly cited) and Iaccheri et al (US 4,753,804; newly cited). Applicant traverses this ground of rejection by amendment and argument.

Without agreeing with the Examiner, but merely to further prosecution, Applicant has amended the claims as shown above. The cited art (alone or in combination) does not teach each and every element of the claimed invention as amended. *See* MPEP 2141.01 and 2143. Thus a *prima facie* case of obviousness cannot be made with respect to the amended claims based on the cited art.

Even if a *prima facie* case of obviousness could be made, the unexpected benefits achieved by Applicant's claimed invention would be sufficient to rebut the *prima facie* case.

Applicant's specification as filed teaches a highly significant combination of properties arising from Applicant's claimed invention and demonstrating unexpected results. *See, e.g.*, Examples 1-3 of the specification as filed.

In the first example, Applicant shows that L-carnitine supplementation together with CHO results in a smaller loss of urinary carnitine than that seen with Control. Total (TC), free (FC) and acyl (AC) carnitine were all excreted less with CHO, than in Control. From the results it can be seen that insulin, released as a result of ingesting carbohydrate (CHO), stimulates L-carnitine retention.

In the second example, Applicant shows that high serum insulin concentration increased sodium dependent L-carnitine transport into skeletal muscle via activation of the Na⁺--K⁺ATPase pump, resulting in a fall in plasma total carnitine.

In the third example, Applicant shows that: (i) Carnitine per se does not readily enter the muscle compartment (even when plasma carnitine concentration is dramatically elevated). This observation is in keeping with the notion that carnitine supplementation per se does not elevate the muscle carnitine pool; and (ii) Insulin promotes muscle carnitine accumulation in the presence of elevated plasma carnitine concentrations.

Thus, Applicant describes for the first time in the specification as filed that Applicant has surprisingly found that administration of carnitine with an agent that increases insulin concentration to a subject results in substantially increased carnitine retention in the tissues of the subject.

These results are often hoped for by researchers but cannot fairly be described as “expected” results. Taken together, the demonstrated beneficial properties and unexpected results are sufficient to rebut the Examiner’s argument that the claimed invention is obvious. None of the cited art, individually or combined, teaches that the claimed invention would provide the benefits shown for the first time in Applicant’s specification.

In conclusion, a *prima facie* case of obviousness could not been made with respect to the claims as amended based on the combination of the cited art in the Office Action. Even if a *prima facie* case of obviousness could be made, the unexpected benefits achieved by Applicant’s claimed invention would be sufficient to rebut the *prima facie* case. Withdrawal of this rejection is respectfully requested.

CONCLUSION

Withdrawal of the pending rejections and reconsideration of the claims are respectfully requested, and a notice of allowance is earnestly solicited. If the Examiner has any questions concerning this Response, the Examiner is invited to telephone Applicant's representative at (206) 389-4535.

Applicants petition for a two (2) month extension of time in the amount of \$490. The Commissioner is hereby authorized to charge Deposit Account 19-2555 for the extension of time fees as well as any additional fees that may be required to render the present submission timely.

Respectfully submitted,

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